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ORIGINAL RESEARCH

Comparison of USG Color Doppler Scan and Conventional Methods (Fundoscopy and Urine ACR) in Assessing Limb Salvation in Diabetic Foot Patients With ABPI<0.5

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ABSTRACT

Introduction: To compare USG Color Doppler scan and conventional methods (fundoscopy and urine ACR) in assessing limb salvation in diabetic foot patients with ABPI<0.5. **Materials & Methods:** The present observational analytical study was conducted during February 2023 to August 2024 at Chhatrapati Shivaji Subharti Hospital among 50 patients with type 2 diabetes mellitus and age above 18 years, having one or the other forms of diabetic foot lesions and foot lesions like gangrene of foot chronic indolent ulcers, cellulitis and abscess with diabetes. Microvascular assessment was done by fundoscopy and urine test for albumin and creatinine ratio. Following standard treatment, patients were followed-up after 2 weeks, 4 weeks and 3 months. By comparing the outcomes of clinical evaluation, microvascular assessment and USG color doppler imaging, correlation was established between the clinical outcome of the patient and three modalities (USG color Doppler, Urine ACR and Fundoscopy). **Results**: Subjects with major amputations also had higher grade of Urine ACR (83.33%) and also had some grade of diabetic retinopathy on fundoscopy. HBA1C of patients with PDR came significantly higher than patients with No evidence of DR (P- value 0.0001) and with grade 1 (mild NPDR) P- value 0.0047. It was observed that urine ACR was raised in subjects along with duration of T2DM and poor glycaemic control.**Conclusion**: It can be concluded that diabetics with higher level of block had higher grade of urine ACR and some grade of retinopathy. Such subjects had poor outcome, so urine ACR and grade of retinopathy can be used as an alternative to USG color doppler in low resource settings where doppler is unavailable or doppler cannot be used due to wound factors as prognostic markers and preventive measures should be taken to reduce these in further follow-ups.

Keywords: USG, Color Doppler scan, Fundoscopy, Urine ACR, ABPI

INTRODUCTION

Diabetes mellitus is a chronic metabolic condition, which is characterized by elevated blood glucose levels resulting from the body's inability to produce insulin or resistance to insulin action, or both. Diabetes affects approximately 500 million people worldwide, around 1 in 11 people. According to the International Diabetes Federation (IDF), India has 2nd highest diabetics after China worldwide. Diabetes and its complications are now becoming reason for increasing morbidity, mortality and burden to health care. Diabetes usually does not gets picked up until patients presents with any complication[1].

The rate of diabetic foot ulceration is higher in developing countries due to various socio-cultural factors such as lack of knowledge regarding diabetic

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foot care, absence of an effective primary health care system and poor socio-economic status.[2-4] Duration of Diabetes is a major risk factor for developing chronic complicated foot ulcers and amputation risk in diabetics.[5-7]

HbA1C is dignified as a marker of glycemic control. Raised levels of HbA1C is associated with increased risk of microangiopathy in diabetics.[8] In addition, a key factor in the development of diabetes complications is glycemic level, both at diagnosis and an "upward drift" in glycemic level over time. People with higher initial HbA1C levels had higher burden of hospital expenses than people with lower levels, and people who experienced higher annual drift in HbA1C levels had even further increased costs.[9] Although the evidence is strong that HbA1C control and reduction can reduce a patient's risk for microvascular complications, the evidence is not so strong that glycemic control greatly reduces a person's risk for cardiovascular complications. Clearly, a combined effort to control blood glucose, blood pressure, and blood lipids will have the greatest effect on reducing a person's risk for diabetes-related complications and, ultimately, will have a favorable impact on the economic costs associated with diabetes.[10-12] The present study was conducted with the following aim and objectives:

1. To compare USG Color Doppler with Fundoscopy and Urine ACR as a prognostic indicator in Diabetic Foot patients.
2. Whether HBA1C (glycemic control) of patients have a role in Diabetic Foot Ulcers (DFU), Diabetic Retinopathy and Diabetic Nephropathy.

MATERIALS & METHODS

The present observational analytical study was conducted during February 2023 to August 2024 at Chhatrapati Shivaji Subharti Hospital, a tertiary care super speciality hospital affiliated with Subharti Medical College, an academic institute of Swami Vivekanand Subharti University. 50 patients meeting the inclusion criteria were included in the study.The research was conducted following a protocol that was approved by the Institutional Review Board for Ethical Clearance at Chhatrapati Shivaji Subharti Hospital/Subharti Medical College/SVS University. Before the start of the study, we had all patients or their representatives sign a written consent form.

Inclusion criteria

1. Patients with type 2 diabetes mellitus and age above 18 years
2. Having one or the other forms of diabetic foot lesions
3. Foot lesions like gangrene of foot chronic indolent ulcers, cellulitis and abscess with diabetes were also included.
4. ABPI <0.5

Exclusion criteria

1. Patients with age below 18 years
2. Patients with foot lesions due to trauma and other ulcers, as well as coronary artery disease (CAD), chronic kidney diseases and associated other co-morbidities.
3. Patients who had undergone arterial graft procedures earlier.
4. Patients giving positive history of smoking and alcohol intake
5. Patients with hypertensive retinopathy.
6. Patients on anticoagulant therapy

Data collection

A pretested proforma was used to collect data on age, sex, history of hypertension, history of smoking and duration of diabetes. Patients having diabetic foot ulcers with ABPI <0.5 were included.Microvascular assessment was done by fundoscopy and urine test for albumin and creatinine ratio. Following standard treatment, patients were followed-up after 2 weeks, 4 weeks and 3 months. By comparing the outcomes of clinical evaluation, microvascular assessment and USG color doppler imaging, correlation was established between the clinical outcome of the patient and three modalities (USG color Doppler, Urine ACR and Fundoscopy).

Statistical analysis

The data was entered into the Microsoft excel sheet and analysis was done using SYSTAT 13.2 software. Descriptive statistics will be calculated in the form of percentages and frequency distribution keeping the value of significance p less than 0.05.

RESULTS

Out of 50 subjects; 37 were males (74%) and 13 were females (26%). Hence there was a preponderance of males in our study. Maximum subjects were 51-60 years (46%), followed by 41-50 years (22%).Maximum subjects were suffering from the disease had a duration between 2 months to 1 year (52%), followed by a duration of less than 1 month (32%). Minimum subjects suffered with the disease for more than 1 year (16%).Maximum subjects had Grade 3 ulcers (36%), followed by Grade 2 (24%). Minimum no. of subjects had Grade 1 ulcer (8%) as shown in graph 1.

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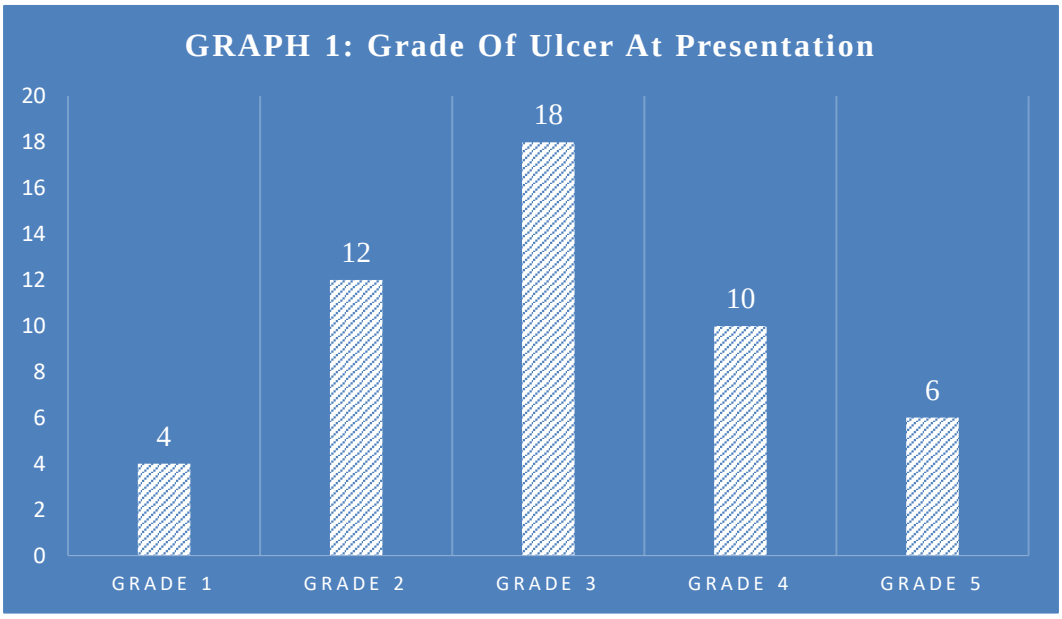

58% of subjects had floaters whereas 42% of subjects complained of diminished vision. Maximum subjects had Moderate NPDR (26%), followed by mild NPDR (24%) as shown in graph 2.

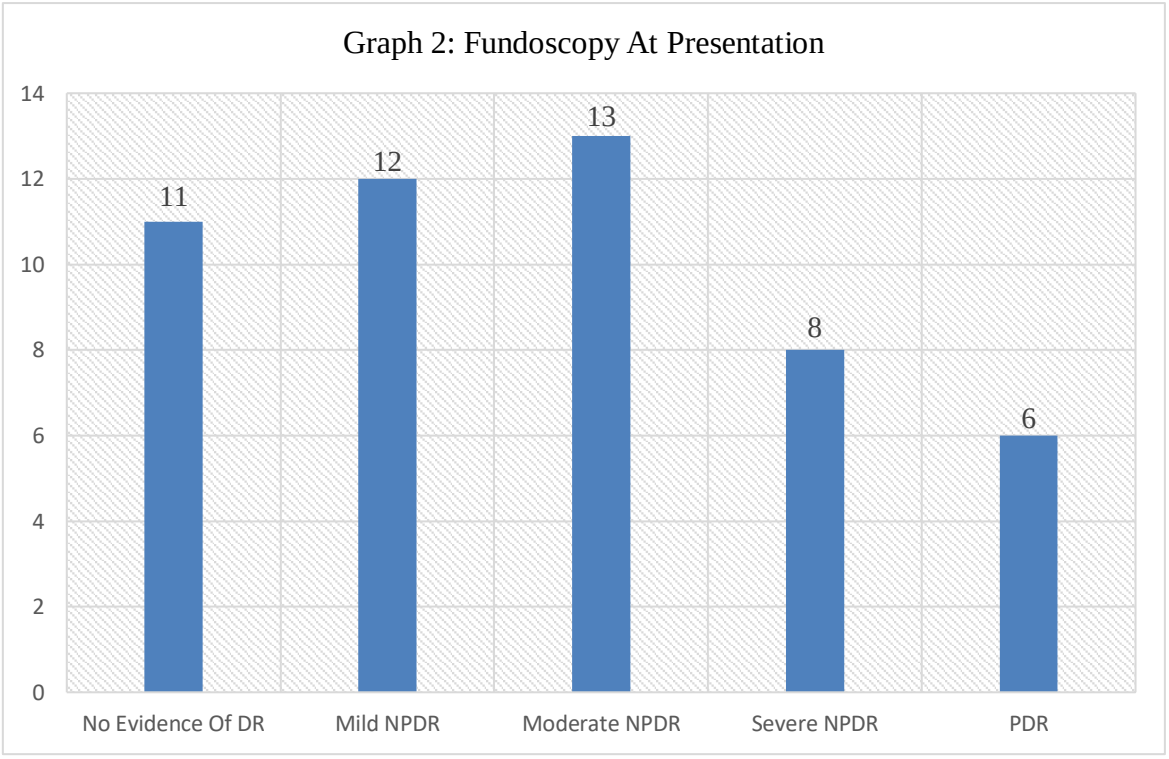

Table 1 shows the intervention performed over the affected limb at the time of study. Maximum patients underwent dressing (24%), patients with higher grade of ulcers and lower ABPI underwent VAC dressing (6%), Above ankle (6%) or below knee amputation (6%).

Table 1: Intervention

Intervention	No.	%
Dressing	12	24
Debridement + Dressing	8	16
Debridement + VAC Dressing	10	20
VAC Dressing	3	6

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Toe Amputation	6	12
Forefoot Amputation	5	10
Above Ankle Amputation	3	6
Below Knee Amputation	3	6
Total	50	100

Out of 50 subjects, 17 (34%) underwent Amputation (major + minor) with mean Urine ACR of 1563.86 and SD 2541.72, whereas 33 (66%) subjects underwent Dressings (Debridement + dressing) with mean Urine ACR of 378.50 and SD 980.58 (table 2). Microalbuminuria of higher grade is associated with higher HBA1C levels.

Table 2: HbA1C and ACR according to amputation

Parameter	Total	Mean	Standard Deviation
HbA1C of Amputees	17	11.14	3.47
HbA1C of Dressings	33	8.81	2.44
Urine ACR of Amputees	17	1563.86	2541.72
Urine ACR of Dressings	33	378.50	980.58

HBA1C of Subjects with PDR came significantly higher than Subjects with No evidence of DR (P value 0.0001) and with grade 1 (mild NPDR) P- value 0.0047 as shown in table 3.

Table 3: Fundoscopy and HbA1C

Grade of Diabetic Retinopathy	No.	HbA1C Mean	SD
No evidence of DR	11	7.009	0.94
Mild NPDR	12	9.2	1.34
Moderate NPDR	13	9.67	2.67
Severe NPDR	8	10.74	2.24
PDR	6	13.5	4.14

Table 4 shows that subjects who had Urine ACR of Grade 3 had some blockage at every level except 1 but maximum subjects 7 (35%) had blockade from the level of CFA. This shows that macrovascular involvement is found to be at a higher level as seen on color doppler in subjects with higher grade of microvascular involvement as depicted by Urine ACR in DFU patients. Subjects with diminished flow at the level of CFA had amputations. Out of 17 subjects underwent amputation (41.17%) who had blockade at the level of CFA, which was found to be statistically significant (P value 0.0022).

Table 4: USG Color Doppler and Urine ACR

USG Color Doppler Level of Diminished Flow	Urine ACR Grade		
	A1	**A2**	**A3**
CFA	0	2 (1- Amputation)	7 (6- Amputations)
SFA	1 (1- Amputation)	0	1 (1- Amputation)
PA	1	2 (1- Amputation)	4 (3- Amputations)
ATA	1 (1- Amputation)	6 (1- Amputation)	2 (2- Amputations)
PTA	0	3	3
DPA	1	3	2
Normal	3	7	1
Total	50		

Table 5 shows that subjects with starting of diabetic retinopathy (Grade 1) and severe NPDR (grade 3) had blockade at the level of CFA 7 (14%). This depicts that both micro and macrovascular complications co-exist in patients with DFU. Subjects who had no evidence of diabetic retinopathy as compared to subjects with moderate NPDR on the basis of outcome had significantly less amputations. (P value= 0.0456).

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Table 5: USG Color Doppler and Fundoscopy

USG Color Doppler Level of Diminished Flow	Fundoscopy Grades				
	Grade 0	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**
CFA	1	4 (4-Amputation)	0	3 (2-Amputation)	1 (1-Amputation)
SFA	0	0	1 (1-Amputation)	0	1 (1-Amputation)
PA	1	2 (1-Amputation)	2 (1-Amputation)	2 (2-Amputation)	0
ATA	2 (1-Amputation)	1 (1-Amputation)	3 (2-Amputation)	1	2
PTA	2	2	0	1	1
DPA	2	0	3	0	1
NORMAL	3	3	4	1	0
TOTAL	50				

Upon evaluation it was found that change in fundoscopy findings in subjects after 3 months follow up was not significant (Table 6).

Table 6: Comparison of fundoscopy

Fundoscopy Findings	At Presentation	At 3 Months
No Evidence Of DR	11	10
Mild NPDR	12	11
Moderate NPDR	13	17
Severe NPDR	8	6
PDR	6	6
Total	50	50

DISCUSSION

In this study, there was a male preponderance in our study. This may be due to the fact that in our society males mostly work outdoors and they work bare foot; thus, are more prone to trauma and formation of DFU. Male predominance was seen in a study "vasculopathy in patients with diabetic Foot using doppler ultrasound" done by Abdul Rahman et al in which out of 30 subjects 22 were male (73.33%) and 8 subjects were female (26.67%).[13]

Diabetic patients are more prone to develop peripheral vascular diseases and neuropathic ulcers with increasing age.[14] In this study, maximum subjects were of the age group 51-60 years 23 (46%). It is similar to a study conducted by T Rathnaganpathi et al in which diabetic foot ulcer was more common among age group of 51-60 years 40 (40%).[15]Similar age prevalence was seen in a study conducted by Rahman A et al[13]15 (50%) subjects were between age group of 56-60 years.

In our study, maximum subjects had Grade 3 ulcers 18 (36%), followed by Grade 2 ulcer 12 (24%) thereafter 10 subjects (20%) had grade 4 ulcers. 6 subjects (12%) had grade 5 ulcers and minimum no. of subjects had Grade 1 ulcer 4 (8%). Our study findings were similar to a study conducted by Ali J et al[16]in which Grade 2 and Grade 3 ulcers were most common and constituted 71.2% of all diabetic foot ulcer grades.A study conducted by BrasilMinistério da Saúde[17], it was found that appropriate blood supply was a crucial factor in ulcer healing and impeding the ulcer infections. However, there was a high prevalence of PVD in diabetics as compared to subjects without diabetes.

Major + minor amputations were performed in 17 (34%) of subjects, remaining 66% subjects had limb salvation. In a multicentric study by Vishwanathan and Kumpatlathere has been high pervasiveness of amputation rates of 65.2%, which include 3, 21, 4 and 3 study centres from North, South, East and West, respectively.[18]In another study by Zubair and Abida et al, they reported 22.5% amputation.[19]A study by Zubair M. et al[20], they depicted an comprehensive amputation rate of 28.4%. Probability of foot amputations can be minimised by achieving good glycaemic control, offloading and well-engineered multidisciplinary foot care, adequate antibiotic selection and proper patient education on foot care.[20]

Luca Dulla Paola et al[21] also reported in their findings that major amputations were independently associated with mortality (HR=7.83 [1.02–59.89]). In our study there was no mortality up to 3 months of follow-

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up.Clinical parameters that allowed us to consider attempt of limb salvation were absence of rest pain and stability of ulcer. Similar findings were found in a study conducted by Baer-Bositis HE et al[22] which showed negative association with healed ulcer and Amputation Free Survival.

During initial examination of subjects, ABPI had significance. But in atherosclerotic patients we find falsely elevated ABPI values, as they exhibit distal Ischemia. Therefore, a need for other investigative modalities should be considered before employing to reconstructive vascular techniques or limb amputation.[16]

In our study, after clinical assessment and ABPI measurement, USG Color Doppler evaluation was done. 9 subjects (18%) showed Common femoral Artery (CFA) involvement, 2 subjects (4%) had involvement from Superficial Femoral Artery (SFA), 7 subjects (14%) had involvement from the level of Popliteal Artery, 9 subjects (18%) had involvement from the level of Anterior Tibial Artery (ATA), whereas 6 subjects (12%) had involvement from the level of Posterior Tibial Artery (PTA) and 6 subjects (12%) had involvement at the level of Dorsalis Pedis Artery (DPA). Remaining 11 subjects (22%) had normal USG Color Doppler Findings. Rahman A et al[13]did Doppler scan in which 17 (56.67%) subjects had involvement of DPA and 19 (63.33%) subjects had involvement of PTA. They did not mention the condition of above arteries. Assumption can be made that there may be some involvement of above arteries.

USG Color Doppler is an essential modality to determine intactness of distal pulses preferably in patients with prospective amputations, as manual palpation may sometimes demonstrate false positive pulses.[23] Measurement of ABPI and USG Color Doppler are elementary non-invasive ways of peripheral vascular estimation in Diabetic foot patients. These investigations are ought to be genuine guide to estimate peripheral vascular narrowing and severity of ischemia. Studies exhibit that ABPI has low sensitivity but high specificity.[24]

A study by Jirkovska A et al.[75] done depicting “the comparison of a simple standardized non-invasive examination of neuropathy and angiopathy with routine diagnostic practice (Doppler ultrasound) in community diabetes clinics for the identification of patients at risk of foot ulceration.” It revealed that cases with angiopathy with impending diabetic foot ulcers (ABPI 0.8) diagnosed, in clinics, 50% had peripheral arterial disease (it depicted 41% cases had claudication, 29% cases had femoral artery bruit and 12% cases had nonpalpable pulsations). Study underlines the noteworthiness of using standardized elementary and non-invasive modality to strengthen the accuracy to ascertain at risk patients for diabetic foot at community level.There is a 20 times higher risk of atherosclerosis in diabetic patients affecting lower limb vessels, hence there is significant reduction in healing of foot ulcer.

Ulcer outcome after 3 months follow-up was as follows- among 28 subjects (56%) the ulcers improved, it was unchanged in 10 subjects (20%) and worsened in 12 subjects (24%). This depicts that poor glycemic control, duration of T2DM and poor compliance to treatment were major factors causing deterioration of diabetic foot ulcer. Similar findings were suggested by “Baqai institute of Diabetes and Endocrinology” depicted that poor glycemic control, duration of diabetes and lack of awareness were major factors in causation of diabetic foot problems.Similar study also confirmed in their results that patients with DFU should also be screened for microvascular complications and major problems can be dealt with proper foot care education.[26]

In current study, subjects were evaluated on the basis of HBA1C who underwent amputation and who underwent dressing. Out of 50 subjects, 17 (34%) underwent Amputation (major + minor) with mean HBA1C of 11.14 and SD 3.47, whereas 33 (66%) subjects underwent Dressings (Debridement + dressing) with mean HBA1C of 8.81 and SD 2.44. P value 0.0081 which was statistically significant. HBA1C was found to be higher in subjects who underwent amputations as compared to subjects who were managed without amputation. Pemayun TG et alin their study also showed that amputation group had higher HBA1C levels as compared to non-amputees with DFU.[27]Poor glycaemic control was found to be a crucial risk factor leading to poor outcome in DFU patients in studies conducted by Zubair M. et al[20] and by Resnick HE. et al.[28]

It was observed in our study that urine ACR was raised in subjects along with duration of T2DM and poor glycaemic control. Similar findings were depicted in a study by AggArwAl J et al[29], Parving HH et al[30]and Hiroki Y et al.[31]

In our study, 17 (34%) underwent Amputation (major + minor) with mean Urine ACR of 1563.86 and SD 2541.72, whereas 33 (66%) subjects underwent Dressings + Debridement with mean Urine ACR of 378.50 and SD 980.58. P value 0.0216 which is considered to be statistically significant.This depicts, that patients who underwent amputation had significantly higher HBA1C than patients in whom limb salvation was possible and also urine ACR was found significantly higher in amputees.Patients who had higher grade of microalbuminuria (A3) when compared to patients with A2 range (30-299) in respect to HBA1C showed significantly higher value. This crossly signifies that DFU patients with uncontrolled Diabetes (high HBA1C) should be evaluated for kidney status through Urine ACR (microcirculation injury).Through our research it was found that higher the level of blockade, higher are the chances of amputation as all the subjects in our study who underwent major amputation- 6 subjects (above ankle and below knee) had blockade at the level of CFA (10%) and SFA (2%).

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All the subjects 9 (18%) who showed blockade from the level of CFA, had Urine ACR grade A3 (7 subjects) or Urine ACR grade A2 (2 subjects), also these subjects except 1 had some grade of Retinopathy. When outcome of these subjects (9) were seen- 7 subjects underwent amputation (major + minor), in only 2 subjects limb salvation was possible with debridement and dressing.

Subjects with major amputations also had higher grade of Urine ACR (83.33%) and also had some grade of diabetic retinopathy on fundoscopy. 11 subjects had minor amputations (toe and forefoot). Out of them 2 subjects had blockade at the level of CFA, 1 subject had blockade at the level of SFA, 4 subjects at the level of PA, 4 subjects at the level of ATA. 23 subjects with normal flow or restricted flow below PTA on color doppler were managed with dressing +/- debridement (limb salvation was possible).

HBA1C of patients with PDR came significantly higher than patients with No evidence of DR (P- value 0.0001) and with grade 1 (mild NPDR) (P- value 0.0047). So, diabetics with higher HBA1C should be evaluated for diabetic retinopathy during their routine follow-up for early diagnosis and prevention.

In our study 9 subjects had block from the level of CFA, when these subjects were evaluated for fundoscopy, it was found that 8 subjects (88.89%) had some grade of retinopathy. In our study, subjects with starting of Diabetic retinopathy (grade 1) and severe NPDR had blockade at the level of CFA 7 (14%). This depicts that both micro and macrovascular complications co-exist in subjects with DFU.

Very less data in review of literature is available that compares multiorgan microcirculation injury in Diabetes patients. More research is required in this direction to evaluate and early diagnosis of complications in these patients.

CONCLUSION

Our study shows that if a diabetic person is having one of the complications of diabetes, he/she must be evaluated for other complications. In our study, 9 (18%) subjects had blockade from the level of CFA out of which 7 (77.78%) underwent amputation. 7 out of 9 subjects had Urine ACR grade A3 and only 2 had Urine ACR grade 2. Except 1 subject, remaining 8 had some grade of Retinopathy. This shows that diabetics with higher level of block had higher grade of urine ACR and some grade of retinopathy. Such subjects had poor outcome, so urine ACR and grade of retinopathy can be used as an alternative to USG color doppler in low resource settings where doppler is unavailable or doppler cannot be used due to wound factors as prognostic markers and preventive measures should be taken to reduce these in further follow-ups.

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